UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
STATESVILLE DIVISION

UNITED STATES *ex rel*. LIUBOV SKIBO, et al., Plaintiffs, v. GREER LABORATORIES, INC., et al., Defendants.	CIVIL ACTION NO. 5:13-cv-110 **Request for Oral Argument**

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT GREER LABORATORIES, INC.'S MOTION TO DISMISS RELATORS' AMENDED COMPLAINT PURSUANT TO RULES 8, 9(B), AND 12(B)(6)

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Pursuant to Federal Rules of Civil Procedure 8, 9(b), and 12(b)(6), Defendant Greer Laboratories, Inc. ("Greer") respectfully submits this memorandum of law in support of its Motion to Dismiss, with prejudice, the Amended Complaint filed by Relators Liubov Skibo and Edward Patt (the "Relators").

Relators filed this action under seal on August 2, 2013 and subsequently filed an Amended Complaint on May 9, 2014. (Dkt. Nos. 1 & 10). After conducting its own investigation, the United States declined to intervene in the matter. (Dkt. No. 25). The twenty-seven states named as plaintiffs likewise declined to intervene. (Dkt. No. 24). The Court unsealed the complaint on April 20, 2016. (Dkt. No. 26). Greer was served with the Amended Complaint on July 19, 2016. (Consent Mot. ¶ 1, Dkt. No. 34).[1]

PRELIMINARY STATEMENT

Relators allege that Greer, their former employer, violated the False Claims Act ("FCA"), 31 U.S.C. § 3729, *et seq.*, by submitting "false" claims (1) for payment for allegedly unlicensed custom mixes of allergen extracts and (2) based on purported violations of current good manufacturing practices ("cGMP") in connection with its pre-commercial, Phase III clinical trials for sublingual immunotherapy ("SLIT"). (Am. Compl. ¶¶ 53-81). Relators also contend that Greer terminated them in retaliation for raising concerns, internally, about various regulatory "violations." (*Id.* at ¶¶ 82-91). Each of these claims is fatally deficient and must be dismissed.

First, Relators' claim that Greer submitted or caused the submission of "false" claims for custom mixes and SLIT fails because Relators do not identify any specific claims for federal or state reimbursement submitted or caused to be submitted by Greer, as required under the FCA and Fed. R. Civ. P. ("FRCP") 9(b). *Second*, Relators' claims regarding custom mixes fail

[1] Greer is the only named defendant who has been served.

because Relators do not plead facts sufficient to plausibly allege that Greer *knowingly* submitted *false* claims in light of the United States Food and Drug Administration's ("FDA") acknowledgement and tacit acceptance of the industrywide practice for manufacturing custom mixes within the applicable regulatory scheme. *Third*, Relators' claim that they were retaliated against for raising internal concerns regarding supposed regulatory issues must be dismissed because Relators have not alleged that they were engaged in "protected activity" having any connection to allegedly fraudulent conduct and a request for payment from the government, let alone that such activity prompted their termination.

In sum, Relators' conclusory and sweeping allegations lack the requisite particularity and do not plausibly state a claim for relief. Accordingly, this Court should dismiss Relators' action in its entirety, with prejudice.

LEGAL STANDARD

To survive a motion to dismiss under FRCP 12(b)(6), a complaint must "contain[] 'enough facts to state a claim to relief that is plausible on its face.'" *Thomas v. Goodwill Indus. of the S. Piedmont*, No. 3:13-cv-0005, 2013 U.S. Dist. LEXIS 102103, at *5 (W.D.N.C. June 17, 2013) (citation omitted). In turn, the plausibility standard requires "more than a sheer possibility that a defendant has acted unlawfully." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Although the court must view the allegations in the light most favorable to the plaintiff, it need not "accept 'legal conclusions couched as facts or unwarranted inferences, unreasonable conclusions, or arguments.'" *United States ex rel. Nathan v. Takeda Pharm. N. Am., Inc.*, 707 F.3d 451, 455 (4th Cir. 2013) (citation omitted); *Iqbal*, 556 U.S. at 678.

A complaint alleging fraud must satisfy FRCP 9(b)'s heightened pleading standard, which requires that the circumstances constituting fraud be pled with particularity. In order to satisfy FRCP 9(b) in FCA cases, a plaintiff "'must, at a minimum, describe the time, place, and

contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby.'" *United States v. Triple Canopy, Inc.*, 775 F.3d 628, 634 (4th Cir. 2015) (citation omitted). Put differently, plaintiffs must allege the "who, what, when, where, and how of the alleged fraud." *Hedley v. Abhe & Svoboda, Inc.*, No. RDB-14-2935, 2015 U.S. Dist. LEXIS 100070, at *10 (D. Md. July 31, 2015). Failure to do so is grounds for dismissal under FRCP 12(b)(6).

Although the Court need not go beyond the four corners of the Amended Complaint to dismiss this case, it may (and should) do so because Relators have selectively and misleadingly incorporated portions of documents into their Complaint. In assessing a motion to dismiss, the court may consider documents that "are quoted, referenced, and relied upon repeatedly" in the complaint. *See In re Wachovia Corp.*, No. 3:09cv262, 2010 U.S. Dist. LEXIS 79971, at *17 n.4 (W.D.N.C. Aug. 6, 2010); *Williams v. Chase Manhattan Mortg. Corp.*, No. 1:04cv199, 2005 U.S. Dist. LEXIS 45605, at *15-19 (W.D.N.C. Oct. 11, 2005). Evaluating a complaint within the context of the extrinsic evidence referred to or relied upon in the complaint enables the court to prevent "'the situation in which a plaintiff is able to maintain a claim of fraud by *extracting an isolated statement from a document* and placing it in the complaint, even though if the statement were examined in the full context of the document, it would be clear that the statement was not fraudulent.'" *Am. Chiropractic v. Trigon Healthcare*, 367 F.3d 212, 234 (4th Cir. 2004) (citation omitted) (emphasis added). This Court has held specifically with respect to FCA cases that it is appropriate at the motion to dismiss stage to consider the entire documentary record and not just those portions selected by the plaintiffs. *See Horne v. Novartis Pharm. Corp.*, 541 F. Supp. 2d 768, 776-77 (W.D.N.C. 2008) ("Because. . .package insert is integral to and explicitly relied on

in the Complaint. . .the entire insert can be considered in a motion to dismiss without converting the motion to one for summary judgment").

In their complaint, Relators repeatedly rely on cherry-picked documents and excerpts in an attempt to support their allegations that Greer's practice of manufacturing custom mixes was misleading or in some way fraudulent. (Am. Compl. ¶¶ 55-56, 60, 62-64, 67, 73-79). Read in context, however, none of the documents or excerpts Relators rely upon even remotely suggest that Greer misrepresented its custom mix practices to anyone, let alone acted fraudulently. Accordingly, in order to fully and properly evaluate Relators' claims the Court should consider in their entirety the following documents referred to or relied upon in the Amended Complaint: (1) Greer's custom mix approval letter ("CMAL") (Exhibit 1); (2) Greer's advertisement of custom mixes and its prescription services from its website at various points in time (Exhibit 2); and (3) Greer's Human Allergy Catalogs from its website (Exhibit 3). (Am. Compl. ¶¶ 54-55, 60, & 73). These documents are attached as exhibits hereto.

RELEVANT ALLEGATIONS

Since its founding as a family-owned company in 1904, Greer has been in the business of manufacturing allergy immunotherapy treatments. (*Id.* at ¶¶ 14-15). Allergy immunotherapy involves physicians injecting patients with allergenic extracts (and mixes of extracts) with the treatment goal that the "patient will develop a tolerance to the allergens, such that the symptoms as a result of exposure to the allergens diminish over time." (*Id.* at ¶ 23). Greer manufactures allergenic extracts under U.S. Government License No. 308 ("Greer's BLA"), which it has held since 1958. (*Id.* at ¶ 27).

A. Allegations Involving Custom Mixes

Custom mixes are mixtures of individual allergenic extracts. (*Id.* at ¶ 53). The extracts used in custom mixes were all individually licensed under Greer's BLA. (*Id.* at ¶ 67). As part of

its allergy immunotherapy treatment business, Greer produced custom mixes upon request from physicians who believed that a number of their patients may require the same mixture of allergenic extracts, often based on the physician's geographic area. (*Id.* at ¶ 54, 64, 68). As Relators concede, Greer manufactured custom mixes very publicly since at least 2001, when Greer advertised custom mixes on its website. (*Id.* at ¶¶ 54 & 73). Relators assert that Greer took certain steps to "create the illusion that the [custom] mixtures are made pursuant to prescriptions for individual patients." (*Id.* at ¶ 60). Relators do not, however, identify any misrepresentations made by anyone at Greer to physicians or the FDA about custom mixes. In fact, Greer separately advertised its custom mixes and prescription products and clearly distinguished between the two types of products in its website and catalogs. *See* Exhibits 2 & 3.

Relators further allege that Greer's custom mixes were produced in the manufacturing division of Greer "pursuant to a generic 'Custom Mix Approval Letter.'" (*Id.* at ¶ 55). In fact, Greer's CMAL was far from "generic." It contains specific information about the licensed physician (such as name and practice information) requesting the mix, the specific licensed extracts to be included in the mix, and the requested dilution. *See* Exhibit 1. The CMAL also described the labeling for the mix. *Id.*

Relators also assert that Greer's custom mixes were "adulterated" because the employees "preparing the custom mixes do not have any specialized training and are not pharmacists or physicians." (Am. Compl. ¶¶ 55-56, 76). They further note that Greer's employees were not supervised by a physician or pharmacist. *Id.* Relators fail, however, to identify any particular employees involved in the manufacturing of custom mixes, their qualifications, or the names or qualifications of those supervising them.

B. Allegations Regarding SLIT

Relators allege that at the time of the Amended Complaint, FDA had only approved the use of allergenic extracts for subcutaneous therapy (injections). (*Id.* at ¶ 33). At that time, according to the Amended Complaint, Greer was seeking FDA approval for oral administration of allergenic extracts under the tongue (sublingual immunotherapy or SLIT). *Id.* As Relators concede because SLIT was in the clinical trial phase and not commercially available, there were "no CPT codes for reimbursement of SLIT." *Id.*

Relators also allege that Greer committed a number of regulatory and cGMP "violations" in connection with its Phase III SLIT studies. (*Id.* at ¶¶ 82-86). The claimed "violations" include (1) switching bottles during the SLIT trials without the proper validation or notation in the IND; (2) a lack of proper effectiveness studies; (3) a lack of proper specifications to release Phase III clinical material; (4) improper storage conditions for the active product; (5) inadequate testing of some vialed active and placebo batches; (6) the failure to have deviations closed before releasing the product for use; and (7) documentation issues which led Relator Skibo to speculate about a "serious 'unblinding' possibility and a potential 'mix up' of placebo and active." (*Id.* at ¶¶ 83-85). Relators do not allege that such "violations" are in any way connected to a claim for payment that was submitted to the government and provide no evidence that any such claims exist.

C. Allegations Regarding Relators' Retaliation Claim

Relators were terminated from Greer in May 2012. (*Id.* at ¶ 91). Relator Skibo was the Director of New Products and Business Development at Greer from November 2008 until October 2009, when she became a Senior Director and the Head of Regulatory Affairs until her termination. (*Id.* at ¶ 21). Relator Skibo claims that she complained to her supervisor that "Greer's compounding pharmacy was not duly and properly licensed in all states in which it was

selling compounding prescriptions." (*Id.* at ¶ 82). Relator Skibo does not identify specific states in which there were alleged licensing deficiencies, nor does she identify any specific licensing regulations or guidelines with which Greer allegedly failed to comply. Relator Skibo further asserts that she noticed a number of regulatory and cGMP "violations" in the SLIT studies, which she brought to the attention of her supervisors. (*Id.* at ¶¶ 82-86). Relator Skibo acknowledges, however, that in response to her request for an investigation, Greer "commissioned two individuals to review [her] cGMP violation concerns," and that after a thorough investigation those consultants concluded that Relator Skibo's concerns were unfounded. (*Id.* at ¶ 87). Unsatisfied with this conclusion, Relator Skibo continued to raise issues with her superiors. (*Id.* at ¶¶ 88-89). Relator Skibo does not assert that the SLIT "violations" were connected to any claims for payment from the government.

Relator Patt was the Director of Compliance at Greer from July 2008 until his termination. (*Id.* at ¶ 22). Relator Patt alleges that in early May 2012, he began raising issues regarding Greer's manufacturing practices with his superior. (*Id.* at ¶ 90). Relator Patt's concerns apparently stemmed from perceived issues with Greer's retention sample practices. *Id*. Relator Patt does not allege that Greer's retention sample practices were in any way connected with fraudulent claims for payment to the government.

ARGUMENT

I. Relators Fail to Plausibly Plead with the Requisite Particularity That Greer Submitted Any Claims for Payment to the Government Relating to Their Allegations, Let Alone Knowingly False Ones.

Relators' FCA claims (Counts 1 and 2 of the Amended Complaint) must be dismissed for two reasons. *First*, Relators fail to identify any specific claims for reimbursement actually submitted to the government by Greer or by others due to Greer's actions – the core requirement of an FCA claim. *Second*, Relators' claims independently fail because even if they had

identified specific claims for payment, their allegations do not support any inference that Greer knew such claims were false. Relators' FCA claims must therefore be dismissed.

A. Relators Fail to Identify Specific Claims for Reimbursement.

It is well settled that fraudulent activity is not actionable under the FCA unless the defendant "call[s] upon the government fisc." *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 785 (4th Cir. 1999) (*Harrison I*). Put differently, "liability under the [FCA] attaches only to a claim actually presented to the government for payment, not to the underlying fraudulent scheme." *Nathan*, 707 F.3d at 456. Accordingly, "when a relator fails to plead plausible allegations of presentment, the relator has not alleged all the elements of a claim under the [FCA]." *Id*. Because a claim under the FCA sounds in fraud, allegations of presentment to the government for payment in violation of the FCA must satisfy the particularity requirement of FRCP 9(b). *Triple Canopy*, 775 F.3d at 634. To comply with FRCP 9(b) in the context of an FCA claim, a plaintiff must allege the "who, what, when, where, and how of the alleged fraud." *Hedley*, 2015 U.S. Dist. LEXIS 100070, at *10. An FCA plaintiff does not satisfy its pleading burden by "alleg[ing] simply and without any stated reason for his belief that claims requesting illegal payments must have been submitted, were likely submitted or should have been submitted to the Government." *Nathan*, 707 F.3d at 456-57. This is particularly true where "a defendant's actions, as alleged and as reasonably inferred from the allegations *could* have led, but *need not necessarily* have led, to the submission of false claims." *Id.* at 457. Rather, the plaintiff must provide '"some indicia of reliability' . . . in the complaint to support the allegation that an actual false claim was presented to the government." *Id.* "[W]ithout such plausible allegations of presentment, a relator not only fails to meet the particularity requirement of FRCP 9(b), but also [fails to] satisfy the general plausibility standard of *Iqbal*." *Id.* Because Relators fail to identify

specific claims for payment submitted for either custom mixes or SLIT, the Amended Complaint must be dismissed in its entirety.

1. Relators Do Not Identify Specific Custom Mix Claims Submitted for Reimbursement.

In this case, Relators offer nothing more than a conclusory allegation that Greer "knowingly caused entities or individuals to submit false and/or fraudulent claims for payments [for custom mixes] to federal and state government programs." (Am. Compl. ¶ 193). Relators fail to identify any specific claims presented to the government for payment for custom mixes or any specific information regarding such claims including by whom, to whom, or on behalf of whom the alleged claims were submitted, or the amounts of any such claims. Relators do not identify the custom mixes for which claims were submitted for federal reimbursement. Nor do they allege which physicians or practices made claims to government payors or the date of any such claims. Instead, Relators ask the Court to infer, solely from the fact that Greer sold custom mixes nationwide to various medical practices, that some unknown physician, at some unknown location in the country, at some point between 2001 and 2014, submitted a claim for payment of an unspecified amount for some custom mix to some government payor. These are precisely the types of sweeping, unsupported, and conclusory allegations that courts have repeatedly deemed inadequate under FRCP 9(b). See *Nathan*, 707 F.3d at 456 (rejecting argument that relator "need only allege the existence of a fraudulent scheme that supports the inference that false claims were presented to the government").

In dismissing the complaint in *Nathan*, the Fourth Circuit rejected similarly vague and conclusory claims, holding that "[g]eneral allegations such as those made here, that unidentified Medicare patients received prescriptions for off-label uses, do not identify with particularity any claims that would trigger liability under the [FCA]." 707 F.3d at 460. The court explained that

it was "unable to infer that a Medicare patient who has received a prescription for an off-label use actually filled the prescription and sought reimbursement from the government. Indeed, '[i]t may be that physicians prescribed [the drug] for off-label uses *only where the patients paid for it themselves or when the patients' private insurers paid for it*.'" *Id.* (emphasis added). *See United States v. Alpharma, Inc.*, No. ELH-10-1601, 2014 U.S. Dist. LEXIS 37172 (D. Md. Mar. 21, 2014) (dismissing claim notwithstanding proof of patient refill requests because relator failed to address the possibility that physicians only prescribed for off-label uses where patients themselves paid for the drug), *vacated on other grounds*, 2016 U.S. App. LEXIS 7525 (4th Cir., 2016). As in *Nathan*, the Relators' allegations of improper submissions for payment fall woefully short of the requisite particularity, and this Court cannot and should not infer a violation from them.[2]

2. Relators Do Not Identify Specific SLIT Claims Submitted for Reimbursement.

Relators' claim that allegations of supposed cGMP "violations" in connection with its Phase III SLIT clinical trials somehow translate into false claims on which FCA liability may be based is utterly unfounded. (Am. Compl. ¶ 83). Relators' claim is fatally flawed because they have not established the availability of any government reimbursement for SLIT. As Relators concede, because SLIT was in the clinical trial phase and not commercially available, there were "no CPT codes for reimbursement of SLIT." (*Id.* at ¶ 33). Thus, Relators do not, and cannot, identify any claims for payment submitted to the government, let alone false ones. *See Harrison*

[2] Relators' allegation that Offutt Air Force Base purchased custom mixes from Greer does not cure this defect. Relators do not identify any claims for payment submitted to or by anyone at Offutt Air Force Base, making it just as likely that custom mixes were provided only where patients paid for the custom mix themselves or had private insurance.

I, 176 F.3d at 785 ("[FCA] at least requires the presence of a claim – a call upon the government fisc – for liability to attach").

B. Relators Do Not Sufficiently Plead that Greer Engaged in Fraudulent Conduct.

Even if Relators had sufficiently pleaded the submission of a claim for payment by the government, which they have not, their claims would still fail because their allegations do not support an inference that such claims were false or that Greer knew they were false, both essential elements of an FCA claim.

1. Relators Do Not Sufficiently Plead That Greer's Custom Mix Practice Resulted in Objectively False Claims.

In order to state a claim under the FCA, the plaintiff must plead that the claim submitted to the government is false. To satisfy this requirement, "the statement or conduct alleged must represent an objective falsehood." *United States ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 376 (4th Cir. 2008). Courts have routinely held that "imprecise statements or differences in interpretation growing out of a disputed legal question are . . . not false under the FCA." *Id*. at 377. *See United States ex rel. Phalp v. Lincare Holdings, Inc.*, 116 F. Supp. 3d 1326, 1343 (S.D. Fla. 2015) ("FCA liability should not be invoked lightly; it is 'not a vehicle to police technical compliance with complex federal regulations'") (citation omitted). Given FDA's longstanding knowledge of and apparent acquiescence to custom mix practices across the industry, Relators have, at most, established that the alleged "falsity" here turns on a disputed legal question. Accordingly, Relators cannot sustain their burden under FRCP 9(b).

(i) Greer's Manufacturing of Custom Mixes Was Consistent with FDA Regulations and Guidance.

The entire regulatory record referenced in the Amended Complaint—and not just those selections embraced by Relators—does not support their conclusory assertion that Greer's

custom mixes were "unapproved." An essential premise of Relators' custom mix claims is that Greer's custom mix practices were not approved by FDA and violated FDA regulations. Thus, Relators allege that "of significant importance" to their claims is the fact that "FDA has further made clear [in 21 C.F.R. § 610.17] that it is not permissible for biologics manufacturers to combine licensed biological products with other licensed biologics products unless there is a separate license for the combined product." (Am. Compl. ¶ 41). In fact, the regulatory scheme is not as simplistic as the Relators portray, and at best identifies a dispute of law which cannot sustain an FCA claim. Relators neglect to mention in their Amended Complaint that although § 610.17 was enacted in the 1940s, it was not clear whether it applied to the practice of custom mix manufacturing and licensing until very recently. Notwithstanding extensive reviews of allergenic extracts over many decades, it was not until 2015 that FDA first "made clear" that it was impermissible to manufacture custom mixes without a separate license for each mix.[3] *See* 80 Fed. Reg. 8881 (Feb. 19, 2015);[4] *United States ex rel. Purcell v. MWI Corp.*, 807 F.3d 281, 287 (D.C. Cir. 2015) (defendant cannot be liable under FCA when first notice of incorrect interpretation of law came "long after the conduct giving rise" to case occurred).

Applicable regulations and guidance promulgated *after* the enactment of § 610.17 show that FDA expressly recognized the validity of allergen mixtures, which led to the industrywide belief that such mixtures were properly manufactured without separate licenses. First enacted in 1973, 21 C.F.R. § 680.3(b)(1) states that "stock concentrate is an extract derived from a single allergenic source and used in the manufacture of more than one lot of product, from which final

[3] "[T]he Court may take judicial notice of and consider the public records of the FDA . . . without transforming this motion [to dismiss] into a motion for summary judgment." *Horne*, 541 F. Supp. 2d at 777.

[4]The 2015 Draft Guidance, titled "Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application," is available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM434176.pdf.

dilutions or *mixtures*, are prepared directly" (emphasis added). FDA Guidance issued in 1999 also acknowledged the practice of manufacturing custom mixes when it defined "biological drug product" in part as "the single or *mixed* allergen extract individually filled, *mixed with other allergens*, diluted, absorbed to alum, or lyophilized in the final container." *See* 1999 Guidance, at 2 (emphasis added) [5]; 64 Fed. Reg. 20006 (Apr. 23, 1999). The 1999 Guidance further suggests that "if any proprietary preparations or *mixtures* are used as components, the information should include a complete statement of composition and other information that will properly describe and identify these materials." 1999 Guidance, at 12 (emphasis added). Such guidance makes clear that custom mixes were, in fact, contemplated and consistent with § 610.17.

Moreover, there was an industrywide belief that custom mixes were properly manufactured without separate licenses, as evidenced by publicly available materials relating to a comprehensive FDA review of biologics in 1972. At that time, FDA began reviewing the effectiveness of all biological products licensed prior to July 1, 1972. *See* Procedures for Review of Safety, Effectiveness, and Labeling, 37 Fed. Reg. 16679 (proposed Aug. 14, 1972); 21 C.F.R. §§ 610.25-26 (Nov. 1973). The FDA Allergenics Panel (the "Panel") evaluated the safety and effectiveness of allergenic extracts, reviewed the labeling of biological products, and submitted a report containing its conclusions and recommendations to the FDA Commissioner. *Id.* at § 610.25(a). The retrospective review process spanned several decades, throughout which the Panel held numerous meetings. *See* Implementation of Efficacy Review, 50 Fed. Reg. 3082, 3083 (Jan. 23, 1985); 76 Fed. Reg. 59407, 59408 (Sept. 26, 2011). The Panel's findings and

[5] The 1999 Guidance, titled "Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for an Allergenic Extract or Allergen Patch Test," is available at http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Allergenics/ucm072451.htm.

recommendations indicate that the Panel was well aware that allergenic extract manufacturers had long marketed various mixtures of extracts, including mixtures that were not based on individual patient prescriptions. *See* 50 Fed. Reg. at 3107-08, 3283-85. In 1985, after reviewing the findings and recommendations of the Panel, FDA issued a Federal Register Notice which addressed the manufacturing of mixtures and distinguished between custom mixes and named-patient prescriptions. *See id.* at 3083. FDA defined "fixed combination allergenic product" in part as "an allergenic product which is prepared by *mixing stock concentrates* . . . ." *Id.* at 3085 (emphasis added). The proposed rule explicitly recognized the practice of making custom mixes as distinct from named-patient mixes. FDA specifically disagreed with the Panel's recommendation that mixtures should be limited to those prepared per a physician's prescription and disagreed with the Panel that there should be a limit on the number of components in a mix product. *Id.* at 3285 ("FDA does not agree that mixed extracts for therapy must, without exception, be limited to mixtures prepared by a physician's prescription . . ."). The 1985 notice reflects that FDA proposed that fixed combination mixtures "be placed in regulatory categories corresponding to the categories recommended for the individual extract." *Id.* at 3108. Put differently, FDA proposed that mixtures be considered safe and effective if the individual components are considered safe and effective. FDA terminated the review in February 2016 without any further discussion of custom mixes. *See* 81 Fed. Reg. 7445 (Feb. 12, 2016).

(ii) FDA Had Explicit Knowledge of Greer's Custom Mix Practices.

Moreover, FDA had explicit knowledge of Greer's particular custom mix manufacturing practices beyond its knowledge of the industry's custom mix practices more generally. As Relators point out, for years Greer publicly advertised its manufacturing and sale of custom mixes. (Am. Compl. ¶ 54). Relators do not, however, plead facts suggesting that Greer in any

way misled physicians or the FDA regarding the approval status of custom mixes. Given FDA's over forty-year history of acknowledging, and never prohibiting, the manufacture of custom mixes without a separate license, Relators have, at best, simply identified a disputed legal question regarding the regulatory scheme, which cannot sustain their burden under FRCP 9(b).

2. Relators' Allegations Do Not Support an Inference That Greer Knowingly Submitted False Claims.

Furthermore, even accepting Relators' strained reading of the relevant regulations, FDA's longstanding awareness of custom mix practices undermines any assertion that Greer *knowingly* submitted false claims, an essential element of an FCA claim. Under the FCA, a defendant acts "knowingly" when he "(1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information." *United States ex rel. Harrison v. Westinghouse Savannah River Co.,* 352 F.3d 908, 913 (4th Cir. 2003) (*Harrison II*). Importantly, courts routinely recognize that the FCA "is not intended to 'punish honest mistakes or incorrect claims submitted through mere negligence.'" *See United States ex rel. Ubl v. IIF Data Sols.*, 650 F.3d 445, 452 (4th Cir. 2011). In fact, "[t]o take advantage of a disputed legal question, as may have happened here, is to be neither deliberately ignorant nor recklessly disregardful." *United States ex rel. Hagood v. Sonoma Cty. Water Agency*, 929 F.2d 1416, 1421 (9th Cir. 1991); *United States v. Medica-Rents Co.*, 285 F. Supp. 2d 742, 772-75 (N.D. Tx. 2003) (government failed to prove knowledge where ample evidence suggested defendants believed they were using the appropriate billing code and "there was considerable confusion within . . . the industry as a whole" regarding the code). Regardless of whether Greer's interpretation of the relevant regulations and guidance was correct, there are simply no allegations suggesting that anyone at Greer acted deliberately or with reckless disregard. In fact, Relators' Amended Complaint is utterly devoid of any allegations

even remotely suggesting the requisite knowledge on the part of anyone at Greer, let alone allegations that satisfy the particularity requirement of FRCP 9(b). For this reason and the reasons discussed *supra* at pages 11-14, Relators cannot support an allegation that Greer knowingly made a false claim to the government.

II. Relators Fail to Plead State FCA Claims with the Required Particularity.

Relators' state FCA claims are based upon the same conclusory allegations underlying their federal FCA claims and thus, fail for the same reasons. The elements of the twenty-seven state false claims statutes at issue generally track those in the federal FCA and courts have interpreted them consistently. Accordingly, for the same reasons the federal FCA claims must be dismissed, Relators' state FCA claims must also be dismissed. *See United States v. Takeda Pharm. Co.*, Nos. 10-11043-FDS, 2012 U.S. Dist. LEXIS 156752, at *20-21 (D. Mass. 2012) (dismissing state FCA claims for same reasons as federal FCA claims where relator failed to allege "how any of the state statutory regimes . . . differ from the federal [FCA] . . .").

III. Relators Have Failed to State an Actionable Claim for Retaliation.

Relators' retaliation claim is also deficient. Although not subject to FRCP 9(b)'s heightened pleading requirement, a plaintiff must still plausibly allege that "(1) he took acts in furtherance of a qui tam suit; (2) his employer knew of these acts; and (3) his employer [took adverse action against] him as a result of these acts." *Mann v. Heckler & Koch Def., Inc.*, 630 F.3d 338, 343 (4th Cir. 2010). Because Relators cannot show that their complaints were linked to a claim for payment submitted to the government, their retaliation claims must be dismissed.

A. Relators Did Not Engage in Protected Activity.

In evaluating whether an employee has satisfied the protected activity prong, the court applies the distinct possibility standard, which requires an employee to show "that he was investigating 'matters that reasonably could lead to a viable FCA action.'" *United States ex rel.*

Rector v. Bon Secours Richmond Health Corp., No. 3:11-CV-38, 2014 U.S. Dist. LEXIS 52161, at *40 (E.D. Va. Apr. 14, 2014). "While the distinct possibility standard is objective, it is applied from the perspective of the facts known by the employee at the time he engaged in the allegedly protected activity." *Weihua Huang v. Rector & Visitors of the Univ. of Va.*, 896 F. Supp. 2d 524, 549 (W.D. Va. 2012). Although "[a] protected activity need not indicate that an actual FCA suit was being contemplated . . . it must evince some attempt to expose possible fraud." *Rector*, 2014 U.S. Dist. LEXIS 52161, at *39. "A general allegation of fraud does not suffice; there must be a submission of a false claim." *See United States ex rel. Brooks v. Lockheed Martin Corp.*, 423 F. Supp. 2d 522, 530 (D. Md. 2006) ("[t]here must be a 'nexus' between the protected actions that the employee takes and exposing fraud or false claims"); *Scates v. Shenandoah Mem'l Hosp.*, No. 5:15-cv-00032, 2015 U.S. Dist. LEXIS 141526, at *14 (W.D. Va. Oct. 19, 2015) ("[t]o engage in protected activity, [plaintiff] must do more than raise broad questions or concerns about internal policies and procedures"); *Farmer v. Eagle Sys.& Servs.*, NO. 5:14-CV-403, 2015 U.S. Dist. LEXIS 2492, at *13 (E.D.N.C. Jan. 9, 2015).

In *Mann*, the plaintiff alleged that he was retaliated against for voicing concerns about violations of federal contracting regulations, including "submitting a non-conforming bid and delivering [a part of the application] after the close of bidding." 630 F.3d at 347. The court rejected this claim, finding that Mann failed to allege that his employer made any false statements or in any way attempted to mislead the government. *Id.* at 346. Importantly, the court emphasized that "the FCA does not empower courts to adjudicate strategic business decisions and to protect the dissenters from these decisions from all consequences. The FCA's scope is commensurate with its purpose. It covers only fraudulent claims against the United States; without fraud, there can be no FCA action." *Id.* at 345-46.

Here, Relators' internal reports regarding supposed regulatory "violations" do not support their retaliation claims. GMP or regulatory violations, without more, typically cannot result in FCA liability. To allow them to do so "would sanction use of the FCA as a sweeping mechanism to promote regulatory compliance, rather than a set of statutes aimed at protecting the financial resources of the government from the consequences of fraudulent conduct." *United States ex rel. Rostholder v. Omnicare, Inc.*, 745 F.3d 694, 702 (4th Cir. 2014); *United States ex rel. Campie v. Gilead Sci., Inc.*, No. C-11-0941 EMC, 2015 U.S. Dist. LEXIS 1635, at *30 (N.D. Cal. Jan. 7, 2015). Where an agency, like FDA, has "broad powers to enforce its own regulations . . . allowing FCA liability based on regulatory non-compliance could 'short-circuit the very remedial process the Government has established to address non-compliance with those regulations.'" *Rostholder*, 745 F.3d at 702. Further, Relators have not alleged that the internal complaints regarding cGMP and manufacturing issues were related to any activity that could plausibly constitute a violation of the FCA. *See Weihua Huang*, 896 F. Supp. 2d at 550 (internal reports only satisfy protected activity prong where report alleges "that there has been a fraud on the government"); *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 237 (1st Cir. 2004) (complaints regarding regulatory violations cannot form the basis of an FCA retaliation claim unless linked to an employer's "knowing submission of false or fraudulent claims for payment to the government").

B. Greer Did Not Have Notice of Any "Protected Activities."

In any event, Relators' claim further fails because they do not allege facts indicating that Greer had notice of their "protected activities." The notice prong "is viewed from the employer's perspective, and 'turns on whether the employer . . . is on notice that litigation is a reasonable possibility.'" *Scates*, 2015 U.S. Dist. LEXIS 141526, at *17 (citation omitted).

Relators allege that on numerous occasions, they reported regulatory and manufacturing "issues" to their superiors. (Am. Compl. ¶¶ 82-90). However, as noted, Relators do not allege that these "issues" were connected to any type of fraudulent activity. As such, Relators failed to allege that Greer "had a reasonable belief that [Relators were] either contemplating a qui tam action or seeking to prevent a violation of the FCA." *Scates*, 2015 U.S. Dist. LEXIS 141526, at *19. *See Rector*, 2014 U.S. Dist. LEXIS 52161, at *41 ("[m]erely grumbling to the employer about . . . regulatory violations does not satisfy the [knowledge] requirement—just as it does not constitute protected activity in the first place"). For these reasons, Relators' retaliation claim must also be dismissed.[6]

CONCLUSION

For all of the reasons presented above, Greer respectfully submits that Relators' Amended Complaint should be dismissed in its entirety, with prejudice.

[6] Even were Relators to adequately allege they took actions in furtherance of protected activity and that Greer had notice of such "protected activity," Relators would still need to allege a causal connection between the protected activity and their termination, which they have failed to do here.

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the CM/ECF system will be served electronically to the registered CM/ECF participants as identified on the Notice of Electronic Filing (NEF) and a paper copy will be sent by certified mail, return receipt requested, to those indicated as non-registered participants as follows:

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